PATENT APPLICATION

Our Docket No. 990356.CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App	:	Stephen Nuss	:	
Serial No.	:	09/760,136	:	Art Unit 3736
Filed	:	January 12, 2001	:	Examiner Jonathan M. Foreman
For	:	TITANIUM MOLYBDENUM ALLOY GUIDEWIRE		

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Sir:

Jeffrey W. Chambers, M.D. declares as follows:

1. I am a practicing cardiologist with extensive experience in the use of guidewires in patients. I perform over 350 angioplasties each year and average 1.7 guidewires per case.
Attached hereto as Exhibit A is a copy of my curriculum vitae establishing my education, training and experience qualifying me to render the opinions expressed herein.

2. I have worked in research on new guidewires and other devices for Medtronic, Inc. a leading company in the medical device field and for several other device companies. Further, I have been engaged in inventing several new designs for guidewires.

3. I have tested the guidewires in the above titled application and have been engaged as a medical advisor. At present I have no equity interest in the applicant's assignee company, but will receive a sales commission from applicant's assignee company if Medtronic, Inc. purchases guidewires or patent rights from the applicant's assignee.

4. I routinely perform cardiac diagnostic procedures, coronary angioplasty and other interventional proceedures in which guidewires are used. I am familiar with guidewires and stents. As indicated, I use guidewires and stents in my medical practice and I am familiar with the medical literature relating to guidewires and stents.

5. In the field of guidewires there is no issue with nickel sensitivity in the body. Many guidewires in popular use today have nickel in them without causing any allergic reactions.

Indeed guidewires containing nickel are in wide use and there is no literature that I am aware of indicating a sensitivity to nickel in association with their use. The reasons for this are that there is relatively limited dwell time of guidewires in the body, most are in place for less than one hour. Even with permanently implanted Atrial Septal Defect (ASD) closure devises, used to repair holes in the heart, with a high nickel content (55%), I am not aware of any reported cases of nickel sensitivity. Secondly guidewires are usually coated with lubricous material such that the surface of the guidewire itself is not exposed to body tissue and therefore will not cause an allergic reaction.

6. As a person skilled in the art of guidewires I would not try to specifically find a material that has no nickel content. The problem of nickel sensitivity in response to guidewires is non-existant.

7. I have tested the guidewires, that are made in accordance with the teachings of the above titled invention and have found them to have superior properties when compared to stainless steel guidewires and nickel titanium guidewires.

The titanium molybdenum alloy guidewires of the present invention has properties between that of stainless steel and nickel titanium guidewires. The titanium molybdenum alloy guidewires claimed in the above captioned application incorporate the best qualities of stainless steel and nickel titanium guidewires without having the drawbacks.

The titanium molybdenum alloy guidewires made in accordance with the present invention have good torque, such that when one end of the guidewire is rotated the other end rotates in a 1 to 1 ratio. The guidewires can therefore be more precisely controlled when torqued.

The titanium molybdenum alloy guidewires made in accordance with the present invention have less memory (tendency to straighten) than nickel titanium guidewires making them easier to use in a tortuous vessel and thus reducing friction that may cause trauma to the vessel wall. The reduced friction also allows for faster and smoother catheter and device delivery. It has more memory than stainless steel so that it is bendable into desired shapes particularly at the tip, which is useful for manual shaping of the guidewire by the cardiologist for different uses.

Titanium molybdenum alloy guidewires have more kink resistance than stainless steel guidewires thus reducing the need to replace guidewires during procedures.

Titanium molybdenum alloy guidewires are also more easily soldered, welded or shaped in the manufacturing process allowing for reduced cost and enhanced clinical features than nickel titanium guidewires.

Titanium molybdenum alloy guidewires are more flexible than stainless steel guidewires so that they will bend or track in the patient's blood vessels and are better able to negotiate tortuous routes inside blood vessels.

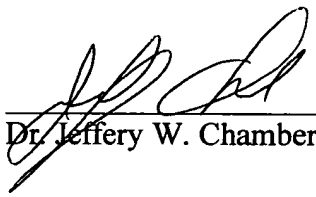
8. Medtronic, Inc., a large medical products company, is currently testing the titanium molybdenum alloy guidewires of the above identified application because they have unique clinical and marketing features, that are deemed better than either stainless steel guidewires or nickel titanium guidewires which are currently in use.

9. The titanium molybdenum alloy guidewires of the above titled invention appear to me to be an improvement over the prior art guidewires. To the best of my knowledge and belief no one in the guidewire manufacturing business or in the titanium molybdenum alloy wire business has heretofore used or proposed to use titanium molybdenum alloys in fabricating guidewires. It is my opinion, based on having worked with the prior art guidewires as well as the guidewires claimed in the present application and comparing their performance had the invention been obvious from the prior art others would have arrived at the invention.

10. The art relating to stents and the art relating to guidewires are totally unrelated as stents have the properties of providing a small radial cross section device, which can be radially expanded to provide scaffolding at the site of a blockage in an artery after being introduced to the body. The desired properties of a stent are not useful properties in the design of medical guidewires. For example stents do not require tractability or torque.

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the Unites States Code, and that such willful false statements may jeopardize the validity of the above-references application or any patent issuing thereon.

April 20, 2004



Dr. Jeffery W. Chambers

EXHIBIT A

JEFFREY W. CHAMBERS, M.D.
CURRICULUM VITAE

BIOGRAPHICAL

Home Address:	18500 Sixth Street North Plymouth, MN 55447 (763) 476-6161
Business Address:	Metropolitan Cardiology Consultants The Heart Center, Suite 120 4040 Coon Rapids Boulevard Minneapolis, MN 55433 763-427-9980 763-427-0904 (fax)
Date of Birth:	August 27, 1962
Present Position:	Interventional Cardiologist Metropolitan Cardiology Consultants Minneapolis, MN
Active Hospital Affiliations:	Mercy Hospital, Minneapolis, MN Unity Hospital, Fridley, MN Buffalo Hospital, Buffalo, MN Abbott Northwestern Hospital, Minneapolis, MN

EDUCATION & TRAINING

1995-1996	Interventional Fellow Department of Medicine—Cardiovascular Division University of Minnesota Medical School Minneapolis, MN
1992-1995	Fellowship in Cardiovascular Diseases Department of Medicine—Cardiovascular Division University of Minnesota Medical School Minneapolis, MN
1989-1992	Internship and Residency in Internal Medicine Department of Internal Medicine University of Minnesota Medical School Minneapolis, MN
1985-1989	Doctor of Medicine Wayne State University Detroit, MI

1981-1985 BS with Honors
Michigan State University
East Lansing, MI

CERTIFICATION

1999 Diplomate, Interventional Cardiology—American Board of Internal Medicine
1995 Diplomate, Cardiovascular Diseases—American Board of Internal Medicine
1992 Diplomate, Internal Medicine—American Board of Internal Medicine
1990 National Board of Medical Examiners

PREVIOUS POSITIONS

1995-1996 Staff Physician, Department of Internal Medicine/Division of Cardiology
University of Minnesota
Minneapolis, MN

1995-1996 Staff Physician, Department of Internal Medicine/Division of Cardiology
Hennepin County Medical Center
Minneapolis, MN

SCHOLARSHIP

Published Papers

Chambers JW, Voss GS, Snider JR, Meyer SM, Cartland JL, Wilson RF: The direct in vivo effects of nitric oxide on the coronary circulation. Am J Physol, 1996; 271(4 Pt 2):H1584-93.

Chambers JW, Denes P, Dahl W, Olson DA, Galita D, Osborn MJ, Titus JL. A familial sudden death syndrome with an abnormal signal averaged electrocardiogram as a potential marker. Am Heart J, 1995;130(2):318-23.

Chambers JW, duCret RP, Bowers TR, Engler CE, Bache RJ and Haidet GC. Pectus exavatum: Abnormal exercise scintigraphy with normal coronary arteries. J Nuc Med, 1994; 35(12):1985-1988.

Abstracts

Chambers JW, Dippel EJ, Pink V, Shammas NW, Takes VS, Youngblut MM. Novel dosing of Abciximab enhances peri-procedural platelet inhabition. Observations from the Heat Study. 2003.

Dippel EJ, **Chambers JW**, Shammas NW, Pink V, Takes VS, Youngblut MM. Heparin coating eliminates acute thrombosis (Heat Study). Pilot Safety Study, 2003.

Chambers JW, Dulas DD, Stark RP, Novicki JS. Device combination approach to difficult lesions, the rota/cut procedure. Am J Cardiol 2002 (suppl A): 109H

Chambers JW, Voss GS, Snider JR, Linstrom PJ, Wilson RF. Nitric oxide is a prererential subendocardial vasodilator. J Am Col Cardiol, 1995; 73A:915-79.

Shear WS, Christensen B, Iacarella C, Marion R, **Chambers JW**, Haidet G, Voss G, Wilson RF. Measurement of systemic nitric oxide release during exercise and its impairment in microvascular disease. Circulation, 1994; 90(4):I-496.

Chambers JW, Voss G, Snider J, Wilson RW. Transcardiac nitric gradient: A new method for measuring coronary nitric oxide release in humans. Circulation, 1994; 90(4):I-449.

Chambers JW, Denes P, Osborne M, Olson D, Galita D, Titus J. Familial sudden cardiac death with normal QT interval and no structural abnormalities. Circulation, 1993; 88:I-313.

Chambers JW, Madlon-Kay RC. Factors associated with mortality in octogenarians with acute myocardial infarction. Clin Res, 1991; 39:758A.

SCIENTIFIC PRESENTATIONS

Medtronic Technology Exchange June 2003– Embolic Protection
Audiojournal February 2002: Treatment of ST elevation Acute Myocardial Infarction
Mayo Clinic Interventional Conference 2000: Combination Therapy for Treatment of Acute Myocardial Infarction
TCT Faculty 2004

RESEARCH

2004-present	Principal Investigator – ARRIVE study (Boston Scientific)
2004-present	Principal Investigator – Pfizer IVUS Study
2004-present	Principal Investigator – ACUITY Study
2004-present	Principal Investigator – ENDEVOR Study (Medtronic)
2003-present	Sub-Investigator—EMERALD Trial (Medtronic)
2003-present	Principal Investigator—Asteroid Trial
2000-present	Principal Investigator—EASE Trial
2003-present	Principal Investigator—Micro Driver Trial
2003-present	Sub-Investigator—AiMi Trial
2002	Principal Investigator—S8 Trial
2001-present	Principal Investigator—BeStent 2 PAS Trial
	Sub-Investigator—Valiant
2001-present	Principal Investigator—GUARD Trial
2001-present	Principal—PROVE IT Trial
2001-present	Sub-Investigator—Synergy Trial
2001-present	Principal Investigator—SPORTIF Trial
2001-2003	Principal Investigator—HEAT Trial
1999-2001	Sub-Investigator—FASTER Trial
1999-2001	Principal Investigator—PRESTO Trial
1999-2001	Principal Investigator—SUPORT Trial

1999-2000	Sub-Investigator—InTIME II Trial
1999-2000	Principal Investigator—BeStent Trial
1998-1999	Principal Investigator—2nd Symphony Trial
1997-1999	Sub-Investigator—PURSUIT Trial
1997-1998	Sub-Investigator—ADMIRE Trial

ADMINISTRATION

Vice President Metropolitian Cardiology Consultants

Director of Inpatient Cardiovascular Services Mercy Hospital

Director of Research Metropolitian Cardiology Consultants

Director Lipid Clinic Metropolitian Cardiology Consultants